UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,660	09/27/2001	Joachim Buenger	MERCK 2305	9098

23599 7590 06/02/2003

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/936,660	Applicant(s) Buenger
	Examiner Gollamudi Kishore	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of species I in Paper No. 8 is acknowledged. Upon consideration however, the election requirement is withdrawn.

Claims included in the prosecution are 1-15.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

3. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Instant invention concerns with the preparation of either liposomes or emulsions using a micromixer. The term, micromixer appears to have different meanings in the art of pharmaceuticals. The reference of Morrision (US 6,099,864) for example refers a system of microcapsules as 'micromixer' (col. 11, lines 16-24). Instant specification does not provide a specific description of a micromixer. Claim 1 for example recites "liquid components from separate stock chambers are mixed with one another by passing them through a micromixer". Claim 3 recites 'temperature controlled micromixer". According to claim 6,

the components are pumped from the stock chambers and fed into the micromixer through connecting tubes with specific requirements. Claims 14 and 15 claim a gel and a cream respectively produced by the process. From the specification, one cannot determine what apparatus/product applicant is using for the process. One cannot determine whether the micromixer is part of the apparatus or exists separately how the tubes are connected and how the temperature is controlled. Specification does not teach how the micromixer produces the ultimate products of gel and cream from the emulsions and liposomes produced by mixing the two components. The technical features of the apparatus and the micromixer appear to be critical in practicing the process and instant specification does not provide adequate description so as one of ordinary skill in the art would be able to practice the invention without undue experimentation.

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant intends to convey by 'micromixer' in claim 1. Generally the pharmaceutical preparations and cosmetic preparations are used in macro scale and the term 'micro' (in the term 'micromixer') is used to denote minute amounts (that is micro scale). There is no adequate description of the term in the specification. Applicant cites some references in the specification which are not in English and one

cannot determine what the term represents. An adequate description of this is essential since one would expect the function of a micromixer is to mix the components to a homogeneous preparation; however, according to the dependent claim 3, the preparation is stirred after using the micromixer.

'if necessary' in claim 2 is deemed indefinite since it is unclear whether the limitation following this expression is indeed the limitation. Furthermore, instant claims are process claims and the step of how the two liquids are warmed.

Claim 3 recites a temperature controlled micromixer; if this is the same as in claim 1, but temperature controlled, then the examiner suggests amending claim 3 to indicate that.

What is being conveyed through claim 4? Is one or more liquid components mixed with synthetic or semisynthetic oils or the liquid component is an oil? If they are the same, how can one form an emulsion with just one component as the term, 'one' in 'one or more' represents.

Similar is the case with claim 5. This claim recites 'if desired with a further oil phase'. One cannot form an emulsion with just an oil phase.

It is unclear from claims 10-11 where the pumping means is.

Claims 12, 14 and 15 are product claims depend from the process claim 1. The process according to claim 1 leads to either an emulsion or a liposome, but not a cream or a

lotion or a solution or a gel. The dependent claims 12, 14 and 15 which recite these products thus, render them indefinite. Clarification is requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless -**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

6. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa (5,658,578).

Ogawa discloses micro emulsions, lotions, creams and gels (note col. 2, lines 18-25 and example 6-13). Instant claims are product claims and the burden is upon applicant to show that the instant products differ from the prior art products.

7. Claims 1-3, 6, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 145 107.

GB discloses a process of preparation of liposomes. The process involves mixing the two components before use. The components are fed into the mixing chamber with turbulent mixing. The mixing chamber thus, is construed as the micromixer. (note the abstract, page 1, lines 50-55, page 3, line 46 through page 4, line 61, page 5, lines 10-41). Emulsions are disclosed on page. Lines 19-20). Although GB does not explicitly disclose

that the micromixer is temperature controlled, since it is a sealed unit, it is deemed that it meets the requirements of instant claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

9. Claims 4-5, 7, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over ~~JP 60-89414.~~ GB 2145107

Talked to the attorney on 8/6/03

As pointed out above, GB discloses a process of preparation of liposomes and emulsions. The process involves mixing the two components before use. The components are fed into the mixing chamber with turbulent mixing in the mixing chamber. GB does not teach that one of the components is an oil. However, it is art known that emulsions can only be formed when an oily phase is combined with the aqueous phase. Therefore, it is deemed obvious to one of ordinary skill in the art to use an oil, either synthetic or natural, if the desired goal is to prepare an emulsion. GB does not appear to teach tubings from each chamber leading to the mixing chamber. However, in view of the presence of tubings in dispensers to draw out the liquid at the bottom, it is deemed obvious to manipulate the basic teachings of GB with the expectation of obtaining almost entire quantity of the

dispensable material from the chambers. The criticality of warming the components is unclear to the examiner since it would be obvious to one skilled in the art that oils solidify depending upon the room temperature and a solidified oil cannot be dispensed.

The examiner cites the reference of Ford (US 4,776,500) to show the knowledge in the art of using tubings from the containers.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

May 29, 2003